

REMARKS

Applicant thanks the Examiner for his careful review of the application and his helpful comments regarding furthering of prosecution of the application. Applicant has accordingly amended the application. Applicant has also amended the application to correctly indicate SEQ ID NOs as requested by the Office. A paper listing of the sequence listing, a statement under 37 CFR 1.821(f) and an electronic version of the sequence listing are also enclosed with this filing. No new matter has been added.

Claims 1-20, 22 and 23 are pending; claim 21 has been cancelled.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 1 to 23 under 35 U.S.C. §103 as obvious over (Lipton et al., 1994; Oktar et al., 2000; Rajora et al., 1997) in view of (Kennedy, 2002; Ruepp, 2002) and “the admitted state of the art.” Applicant respectfully traverses this rejection because Lipton, Oktar, Rajora, Kennedy or Ruepp, neither singly nor in combination, teach nor suggest combining α -MSH peptides and derivatives thereof with artichoke leaf extract (ALE) for the treatment and prophylactic administration of *malabsorption* disease.

The specification (can claim 2) helps one of skill in the art to understand malabsorptive conditions (as opposed to those conditions that are simply inflammatory):

Many disorders of the GIT can be listed in the category of malabsorption. This list includes, but is not limited to, celiac sprue (gluten-sensitive enteropathy), Crohn's disease, abetalipoproteinemia, Hartnup's disease, tropical sprue, bacterial overgrowth syndrome, cystinuria, monosaccharide absorptive defects, Whipple's disease and infective, immunologic or allergic injury. These disorders vary from specific genetic defects to the acquired diffuse mucosal diseases and represent a broad spectrum of conditions with varying etiologies. Clinical manifestations are equally diverse. *Id.* [(Cecil and Andreoli, 1986) at pp. 267-270]. (Paragraph [0007], (Lipton, 2004))

Rajora *et al.* (1997) investigated the effects of α -MSH in experimental *inflammatory* bowel disease. The mouse model system does not teach anything about α -MSH to malabsorption diseases *per se*. Likewise, Oktar *et al.* (2000) investigated similar phenomena in a rat model system, again the model system mimicking inflammatory bowel disease. Similarly, Lipton *et al.* (1994) also discuss that there is mounting (but apparently not conclusive) evidence that α -MSH inhibits inflammatory reactions in animal models of inflammatory responses in humans (*see* Abstract, lines 8-10). Lipton *et al.* (1994) do not speak specifically to malabsorption diseases.

Applicant also respectfully traverses the Office's assertion that the statement “recent studies indicate α -MSH participates in the anti-inflammatory response in the duodenal mucosa of celiac patients,” citing

paragraph [0014] of the specification (Lipton, 2004) is an admission by Applicant. Pointedly, and as the *MPEP* unequivocally states in §2129 (“Admissions as Prior Art”), “. . . the work of the same inventive entity may not be considered prior art against the claims unless it falls under one of the statutory categories” ((Office, 2004), page 2100-72 (emphasis in original), citing *Riverwood Int’l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003) and *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 650 (Fed. Cir. 1984)). Barring the statement falling under one of the “statutory categories” (which it does not), this statement cannot be held to be an admission. Applicant respectfully requests that the Office’s assertion of the admission be removed from the record.

Not only do Rajora, Oktar or Lipton teach nothing about ALE, they also teach nothing about malabsorption disease.

Ruepp (2002) teaches that ALE is useful in treating inflammatory bowel disease, not malabsorption disorders; likewise, Kennedy (2002) teaches the same. Neither discusses α -MSH nor malabsorption disorders and ALE.

Therefore, one of skill in the art would not be motivated to combine the α -MSH peptides of Lipton, Oktar, or Rajora with the ALEs taught by Ruepp and Kennedy to formulate compositions for the treatment and prophylactic administration for malabsorption GI disorders because the references do not suggest or teach the compounds in the treatment of malabsorption GI disorders.

The Office has also cited *In re Crockett*, 279 F.2d 274, 276-77 (CCPA 1960) (among others) for the proposition that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. However, the Federal Circuit has also noted that “. . . one of skill in the art might find it obvious to try various combinations” does not establish a *prima facie* showing of obviousness. *In re Geiger*, 815 F.2d 686, 688 (Fed. Cir. 1987). “Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive *supporting the combination*.” *Geiger*, 815 F.2d at 688, citing *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 (Fed. Cir. 1984) (emphasis added). The court also noting that “one skilled in the art might find it obvious to try various combinations . . . However, this is not the standard of 35 USC 103.” *Geiger*, 815 F.2d at 688, citing *In re Goodwin*, 576 F.2d 375, 377 (CCPA 1978); *In re Antonie*, 559 F.2d 618 (CCPA 1977) and *In re Tomlinson*, 363 F.2d 928 (CCPA 1966).

Here, the facts are even more disparate than in *Geiger*. Whereas scale formation in water tanks results from relatively simple chemistry—the subject of *Geiger*’s invention—malabsorption is a much more complex phenomenon and is a term of art that refers to disorders with a unifying characteristic of malabsorption (*see* [0007] of (Lipton, 2004)). The 27th edition of *Stedman’s Medical Dictionary* ((Stedman, 2000) at p. 1055) defines malabsorption as “imperfect, inadequate, or otherwise disordered gastrointestinal absorption.” At best, one

of skill in the art would be motivated to try combining ALE and α -MSH—although Applicant ardently emphasizes there is no incentive to do so in the cited references. The Office has engaged in improper hindsight reconstruction.

Whether taken in combination or singularly, neither Lipton, Oktar, Rajora, Ruepp nor Kennedy teach the invention. Applicant respectfully asserts that the Office has engaged in improper hindsight reconstruction of Applicant's claimed invention.

Conclusion

Nowhere in (Lipton et al., 1994; Oktar et al., 2000; Rajora et al., 1997) in view of (Kennedy, 2002; Ruepp, 2002) is there a motivation to combine their teachings that would result in the present invention—combinations of α -MSH and ALE for the treatment of absorption disorders of the GI. As noted above, Applicant respectfully asserts that the Office has engaged in improper hindsight reconstruction of the claimed invention. Applicant respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C. §112, ¶¶1 and 2

The rejections of claims 10-18 under 35 U.S.C. §112, ¶1 are obviated by amendment. The claims have been amended to recite “treating.” The rejections of claims 19-23 under 35 U.S.C. §112, ¶2 are obviated in part by amendment, per the Examiner's suggestion: claim 21 has been cancelled, and claim 19 amended.

Applicant respectfully traverses the Office's rejection of claim 19 under 35 U.S.C. §112, ¶2 for being indefinite regarding the term “derivatives of α -MSH.” Applicant notes that contrary to the Office's assertion that derivatives of α -MSH “could be anything,” Applicant points to, *inter alia*, paragraphs [0034] and [0035], wherein derivatives of α -MSH are discussed. Applicant respectfully requests withdrawal of the rejection.

Non-legal references

Cecil, R.L., and T.E. Andreoli. 1986. Cecil essentials of medicine. Saunders, Philadelphia. xv, 831 p. pp.

Kennedy, J. 2002. Herb Brief: Artichoke.

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Lipton, J.M., G. Ceriani, A. Macaluso, D. McCoy, K. Carnes, J. Biltz, and A. Catania. 1994. Antiinflammatory effects of the neuropeptide alpha-MSH in acute, chronic, and systemic inflammation. Ann N Y Acad Sci. 741:137-48.

Office, U.S.P. 2004. Manual of patent examining procedure. For sale by the Superintendent of Documents, Washington, D.C.

Oktar, B.K., F. Ercan, B.C. Yegen, and I. Alican. 2000. The effect of alpha-melanocyte stimulating hormone on colonic inflammation in the rat. Peptides. 21:1271-7.

Rajora, N., G. Boccoli, A. Catania, and J.M. Lipton. 1997. alpha-MSH modulates experimental inflammatory bowel disease. *Peptides*. 18:381-5.

Ruepp, M. US Patent Application Publication 2002/0012708. 2002. USE OF ARTICHOKE (CYNARA) EXTRACTS.

Stedman, T.L. 2000. *Stedman's medical dictionary*. Lippincott Williams & Wilkins, Philadelphia. xxxvi, [127], 2098 p. pp.

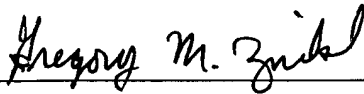
REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicant believes that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned at (312) 627-2126.

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